

connected, to make and/or use the invention as claimed. More specifically, the Action alleges that there is no disclosure on how to use SEQ ID NO:214 for example, in the diagnosis of ovarian cancer, and that the specification only mentions SEQ ID NO:214 once, describing it as the "consensus sequence for O1034C/0591S of 1879 base pairs," the significance of which is not disclosed. Applicants respectfully traverse this ground for rejection.

Initially, Applicants submit that they are somewhat puzzled by the Action's assertion that SEQ ID NO:214, or O1034C/0591S is only mentioned once in the present application. Applicants submit that this sequence is described, for example, on pages 3, 4, 9, 11, 13, 26, 104, 105, and 106-108. As to the Action's assertion that the significance of this sequence is not disclosed, Applicants submit that the present application is directed to Applicants discovery of sequences that are differentially expressed in ovarian tumor tissue versus normal tissues, and the use of those sequences, for example in the detection of ovarian cancer. The instant specification is replete with guidance on both the tumor specificity of the Applicant's polynucleotides and the use of these polynucleotides in the detection of ovarian cancer. The specification, for example on page 105, lines 8 through 11, describes that clone 57887 (SEQ ID NO:199), demonstrated a mean expression signal of greater than 0.4 in 44% of ovarian tumors tested when compared to normal tissues. This corresponds to 4.04-fold over-expression in ovarian tumor tissues compared to normal tissues. The specification further identifies on page 106, line 9, through page 108, line 13, the ovarian antigen O1034C (SEQ ID NO:210). This sequence was identified using electronic subtraction (a technique which is described in detail on page 106, lines 12 through 24 of the present application) wherein sequences that were only seen or primarily seen in ovarian libraries were selected as representing genes that were differentially expressed in ovarian tissue, relative to all normal adult tissue. O1034C was further analyzed using microarray analysis and shown to be over-expressed 4.95 fold in ovarian tumors and normal ovarian samples as compared to normal tissue samples. Further analysis of O1034C (SEQ ID NO:210) and O591S (SEQ ID NO:199) demonstrated that these sequences shared sequence homology, allowing for the construction of an extended consensus sequence that was disclosed in SEQ ID NO:214. Applicants therefore submit, that based on microarray analysis of both SEQ ID NOs:199 and 210, both of which showed over-expression in ovarian samples, and that in fact, SEQ ID NO:214 is also be over-expressed in ovarian tumors (Declaratory support for

which can be provided upon request). Therefore Applicants submit that based on their disclosure of the over expression of O1034C/O591S, one of skill in the relevant art would know how to use the sequences of the present invention for example, in the diagnosis of ovarian cancer. Applicants respectfully request withdrawal of this rejection.

The Action further alleges that cancer diagnosis is a complicated and unpredictable field, and based on that, alleges that it is unlikely that the presence or absence of SEQ ID NO:214 could be diagnostic of ovarian cancer. Applicants respectfully traverse this ground of rejection.

Applicants submit, that as described above, the present application is replete with guidance on how one of skill in the relevant art would use sequences of the present invention, *e.g.*, SEQ ID NO:214, in for example, the diagnosis of ovarian cancer. In fact, Applicants have specifically demonstrated that O1034C/O591S is, in fact, over-expressed in ovarian tumors compared to normal tissue.

The Action further states that many so called “tumor” markers in the art have been shown to be present in non-tumor tissues such that one of skill in the art would not have an expectation that any one sequence would be indicative of cancer. Applicants submit that the present disclosure clearly describes how one could use SEQ ID NO:214, in for example, the detection of ovarian cancer. The Action’s assertion that cancer markers, such as the one presently claimed, have been shown to be present in non-tumor tissues, or are only able to identify a subset of cancers, does not form the basis of an appropriate enablement rejection. Section 2164.08(b) of the M.P.E.P states that:

“The presence of inoperative embodiments within the scope of the claim does not render a claim nonenabled.”

Applicants therefore submit that having established that SEQ ID NO:214 is over-expressed in ovarian tumors compared to normal tissues, and having disclosed how to use this sequence in, for example, the detection of ovarian cancer, the fact that it is not present in all ovarian cancers does not mean that the present claims are not enabled. Applicants accordingly submit that the pending claims are fully enabled under 35 U.S.C. § 112, first paragraph. Reconsideration of the Action’s rejection is thus respectfully requested.

Rejection Under 35 U.S.C. § 102

Claims 1, 3-4, 8, 11-in part, and 15 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by McKee *et al.*, (Genomics (1997) vol. 46, no.3:426-434). More specifically, the Action alleges that McKee *et al.*, disclose a 1359 bp open reading frame from fetal brain cDNA which is complementary to SEQ ID NO:214 at positions 1124-1638, and therefore allegedly meets the limitations set forth in the claims with regard to sequences that hybridize to SEQ ID NO:214 under moderately stringent conditions.

Applicants respectfully traverse this ground of rejection. However, for the purpose of expediting prosecution and not in acquiescence, Applicants have elected to cancel claim 8 and amend claim 1, part (d) to recite "sequences that hybridize to SEQ ID NO:214 under highly stringent conditions. Applicants submit that support for this amendment can be found, for example at page 11, lines 8 through 9, and page 27, lines 13 through 26. Reconsideration and withdrawal of this rejection are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

It is respectfully submitted that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Jiangchun Xu et al.

SEED Intellectual Property Law Group PLLC



William T. Christiansen, Ph.D.
Registration No. 44,614

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031



VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 8 has been canceled.

Claims 1 and 11 have been amended as follows:

1. (Amended) An isolated polynucleotide comprising a sequence selected from the group consisting of:

(a) sequences provided in SEQ ID NO: ~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208, and 210-214;~~

(b) ~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210 the complement of SEQ ID NO:214;~~

(c) sequences consisting of at least 20 contiguous residues of a sequence provided in SEQ ID NO: ~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210-214;~~

(d) sequences that hybridize to a sequence provided in SEQ ID NO: ~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210-214 under moderately highly stringent conditions;~~

(e) sequences having at least 75% identity to a sequence provided in SEQ ID NO: ~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136,~~

~~137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210-214;~~

(f) sequences having at least 90% identity to a sequence provided in SEQ ID NO:~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210-214~~ and

(g) degenerate variants of a sequence provided in SEQ ID NO:~~1, 2, 5, 9, 10, 13, 16, 19, 23, 27, 28, 32, 33, 35, 38, 41-50, 52, 53, 56, 57, 63, 65, 69-72, 75, 78, 80-82, 84, 86, 89-93, 95, 97-100, 103, 107, 111, 114, 117, 120, 121, 125, 128, 132-134, 136, 137, 140, 143-146, 148-151, 156, 158, 160-162, 166-168, 171, 174-183, 185, 193-199, 203-206, 208 and 210-214.~~

11. (Amended) A composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component selected from the group consisting of the polynucleotides of claim 1.:

- (a) ~~polypeptides according to claim 2;~~
- (b) ~~polynucleotides according to claim 1;~~
- (c) ~~antibodies according to claim 5;~~
- (d) ~~fusion proteins according to claim 7;~~
- (e) ~~T cell populations according to claim 10; and~~
- (f) ~~antigen presenting cells that express a polypeptide according to claim 2.~~